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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,910	05/11/2001	Annette Gilchrist	2661-101	4758

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/852,910	Applicant(s) GILCHRIST ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-101 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, 33, 34, drawn to a method of identifying a G protein coupled receptor binding inhibitor, classified in class 435, subclass 7.1.

II. Claims 31-32, (claim 32 improperly depends on claim 33) drawn to ELISA assay, classified in class 435, subclass 7.71.

III. Claims 35, drawn to a compound, classified in class 530, subclass 2+.

IV. Claim 36, drawn to a compound identified by the process of claim 29, classified in class 530, subclass 2+.

V. Claims 37-62, drawn to a method of identifying peptide from a library based on a native GPCR binding peptide, classified in class 435, subclass 7.1.

VI. Claims 63-85, drawn to a method of identifying a G protein coupled receptor signaling inhibitor compound using a library of candidate compounds, classified in class 435, subclass 7.1.

VII. Claim 86, drawn to a G protein coupled receptor signaling inhibiting peptide, classified in class 530, subclasses, 324-327.

VIII. Claim 87, drawn to a peptide inhibitor of G protein coupled receptor, classified in class 530, subclasses 324-330.

IX. Claim 88, drawn to a method of inhibiting G protein coupled receptor in a cell by administering a compound, classified in class 435, subclass 7.1.

X. Claim 89, drawn to a method of inhibiting G protein by administering to a cell a compound obtained from claim 37, classified in class 435, subclass 7.1.

XI. Claim 90, drawn to a method of inhibiting G protein coupled by administering a compound from claim 63, classified in class 435, subclass 7.1.

XII. Claim 91, drawn to a method of inhibiting G protein coupled receptor, classified in class 435, subclass 7.1.

XIII. Claims 92-93, drawn to a method of identifying a G protein signaling modifier compound, classified in class 435, subclass 7.1.

XIV. Claim 94, drawn to a compound, classified in class 530, subclass 327.

XV. Claim 95, drawn to a compound, classified in class 530, subclass 327.

XVI. Claim 96, drawn to a minigene construct, classified in class 536, subclass 23.4.

XVII. Claim 97, drawn to a minigene construct, classified in class 536, subclass 23.4

XVIII. Claim 98-101, drawn to a therapeutic method classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, V, VI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods encompassing different steps that results in different products. The method of Group I, for example, differs from the method of Group II in that an Group II requires an ELISA method for screening for the candidate or non-candidate compound that requires an immobilization of the G protein coupled receptor onto a solid support for analysis, which is not required for Group I, competitive

binding. The method of Group V relates only to identifying a binding peptide, which is not a competitive inhibitor, by direct binding to the G protein coupled receptor (GPCR). Group XIII relates to an entirely different method of identifying a modifier peptide encompassing entirely different process steps from Groups I, II and V-VI. Thus, each method requires different steps, reagents and results in different peptides with different binding affinities.

Inventions III, IV, VII, VIII, XIV, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different peptide compounds. These peptides differ in structure as a result of screening different components of a library. For example, the peptide of Group III is competitor peptides while Group VII are binding peptides. Furthermore, The compounds of Groups III, IV, VII, VIII are obtained from a library while the compounds of XV can be made by chemical or recombinant techniques.

Inventions IX, X, XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods of inhibiting GPCR signal in a cell by which different peptide compounds obtained from different screening methods are administered onto a cell. Therefore, each of the methods would result in different effects since different compounds are employed.

Inventions (III, IV, VII, VIII, XIV and XV) and (XVI and XVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different compounds. The peptide of Groups III, IV, VII, VIII, XIV and XV differ in structure from the structure of Groups XVI and XVII which are nucleic acids or fusion of nucleic acids with vectors or plasmids.

Inventions XVI and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different compounds. The minigene

structure of Groups XVI and XVII differ in structure since each of the products is produced from different libraries.

Inventions (I, II, V, VI, IX, X, XI, XII, XII, XIII and XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods of identifying using screening method, inhibiting, and treating. Thus, each method requires different steps, reagents and results in different products.

Inventions (I, II, V, VI, IX, X, XI, XII, XII, XIII and XVIII) and (III, IV, VII, VIII, XIV, XVI and XVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to subject matters, methods and products. Furthermore, the peptide compounds, as shown by Group XV, can be made by other methods such as recombinant or chemical synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of

their recognized divergent subject matter and the search required for Group I is not required for Groups II-XVIII, (especially since the US Patents and Foreign searches are not co-extensive with literature searches), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. Screening method of library: Elect one from A-E:

A. Testing for binding to an intact GPCR (claim 2) either by activation (claim 21) or inhibition (claim 23).

B. Testing for binding to at least an intracellular fragment of GPCR (claim 3).

C). Sequential binding assays (claim 13).

D). Competitive binding assay (claim 14 or 15)

E). Enzyme-linked immunosorbant assay (claim 20).

2. Binding peptide: Elect A(i) or (ii) and further elect from (ii), if elected:

A. G protein subunit or fragment

i. Based on peptide length from 7-70 a.a. (claims 5-9).

ii. Named subunit:

G alpha subunit (claim 10)

G alpha subunit C-end (claim 11)

G beta dimer (claim 12)

3. Library: Elect a single library from A-F; if F is elected elect from (i) or ii.

A. Combinatorial peptide (claim 24)

B. Protein-peptide fusion protein library (claim 25, species, claim 26).

C. Display library

D. Focused library

E. Peptide library (claim 33)(candidate compounds)

F. Small molecule library (claims 34)

i. Drug-like

ii. Focussed

4. Signaling activity as recited in claim 93, anyone of (a)-(x). (Elect a single signaling activity).

5. Peptide compound of Seq. ID. Nos. 2, 4, 6, 8, 10, 12 etc. as recited in claims 94 or 95. (Elect a single peptide).

6. Nucleic acid compound that encodes anyone of Seq. ID. Nos. 2, 4, 6, 8 etc. as recited in claims 976 and 97.

Each of the species recited in Subgroups 1-5 and the further the sub groupings of these subgroups differs in structure, mode of actions or function, starting materials and etc. that results in different products. The patentability determination of each of these species differs from one another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species **(for each of the subgroups I-5. If the subgroups 1-5 are further subgroups, then elect a single species from those subgroups. For example, a single binding to the intact GPCR, a single library e.g., combinatorial, a single length peptide and a single structure from the different Seq.ID Nos.)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 37, 63, 92, 94, 96 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
October 21, 2002